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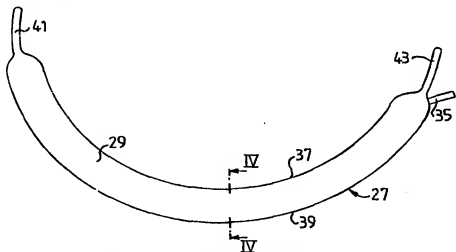
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(54) Title: DEVICE FOR REDUCING THE FOOD INTAKE OF A PATIENT

(57) Abstract

A food intake restriction device for forming a stoma opening in the stomach or esophagus of a patient, comprises a band (27), and means (41, 43) for forming a loop of the band defining a restriction opening. The band (27) comprises a single elongated closed tubing (29) which is devoid of any longitudinally extending reinforcement means at least along a substantial longitudinal portion of the tubing. Means (35) are provided for inflating and deflating the tubing to adjust the size of said restriction opening. Preferably, the tubing (29) is elastic, whereby the band (27) is extensible.



"Device for reducing the food intake of a patient"

The present invention relates to a food intake restriction device for forming a stoma opening in the stomach or esophagus of a patient, comprising a band, and means for forming a loop of the band defining a restriction opening.

In the early 1980s, surgical procedures to treat overweight patients were often carried out by placing a band of a food intake restriction device around the stomach, which formed a restriction, thereby preventing food from passing downwards, or more correctly reducing the speed and the amount of food being eaten. After a few years of use of the new surgical method it became evident that it was very difficult to apply the band with an appropriate tightness - if the band was too tight around the stomach, patients were affected by vomiting attacks. Alternatively, if the band was too loose, the opening between the upper and lower parts of the stomach became too large, resulting in the eating or the weight problems being unaffected. Unfortunately, therefore many of these operations resulted in failure.

The solution to this problem was to provide a band having an inflatable balloon on the inside thereof, like a blood pressure cuff. This balloon could be connected to an injection port, making it possible to change the inside diameter of the band after the operation. In this way, if after operation the band was found to be too tight, it was possible to drain off some fluid through the injection port. This procedure increased the opening of the band loop, resulting in a larger restriction between the upper and lower parts of the stomach. On the other hand, if patients did not lose weight, it was possible to inject fluid through the injection port, thereby narrowing the restriction between the upper and lower parts of the stomach (the "stoma diameter"). This operation was clearly better than the earlier method, but unfortunately this operation was not without problems. Namely, there existed three main difficulties.

First, the loop band had a tendency to dislocate down-

wards towards the lower part of the stomach. This could be prevented by suturing the lower part of the stomach to the upper part of the stomach (called "tunnelling") to prevent the band from dislocating downwards towards the major curvature of the stomach. However, sometimes these sutures ruptured, thus negatively affecting a desired long term weight loss.

The second difficulty, revealed by recent research, was that the upper part of the stomach rapidly increased in size, up to approximately ten times of its original size, resulting in less weight reduction.

The third difficulty was that the prior band tended to migrate through the stomach wall.

An object of the present invention is to provide a simple reliable substantially non-pressurized food intake restriction device for reducing the food intake of a patient.

Another object of the invention is to provide a food intake restriction device in which the band is designed to minimize the risk of the band migrating through the stomach wall.

These objects are obtained by a food intake restriction device of the kind initially stated, which is characterised in that the band comprises a single elongated closed tubing which is devoid of any longitudinally extending reinforcement means at least along a substantial longitudinal portion of the tubing, and that means are provided for inflating and deflating the tubing to adjust the size of said restriction opening. As a result, at least a substantial portion of the band lacks any hard reinforcing outer wall that might injure the stomach. This is of particular advantage when the band is encircled by stomach wall portions because of tunneling sutures. To achieve the necessary adjustment of the size of the restriction opening, the tubing is simply designed broad enough to expand sufficiently from a flattened state radially inwardly of the loop. Besides, a broad tubing is beneficial with regard to the large surface area of the tubing that will contact the stomach.

The circumferential wall of the tubing may be pliable and, which is preferred, elastic, whereby the band is extensible. As a result, the extensible band is able to yield longitudinally to permit accidental large pieces of food to pass through the restriction opening.

Furthermore, the elastic circumferential wall of the band is able to yield radially under the influences of dynamic movements of the stomach, i.e. the stomach has a certain freedom to move where it is in contact with the band, which significantly reduces the risk of the band injuring or migrating through the stomach wall. If the stomach wall were prevented from moving along the region where the band contacts the stomach, the stomach wall would become thinner over time, which dramatically increases the risk of the band penetrating the stomach wall. Thus, the elastic characteristics of the band of the food intake restriction device of the invention results in a more natural cooperation between the band and the stomach, i.e. the muscle of the stomach wall is allowed to move properly in a physiological sense.

The thickness of the circumferential wall of the tubing may suitably vary, preferably continuously, in the circumferential direction, so that two opposite axially extending portions of the circumferential wall differ in thickness. As a result, a relatively greater inward expansion of the tubing is achieved when the band inflates. The thinner one of said two opposite axially extending portions may suitably be designed to form a row of bulges along the band, when the tubing is at least partly filled with fluid. This gives the advantage that the formation of creases on the inner side of the tubing as the band is bent into a loop is avoided, which dramatically increases the life-time of the band.

Furthermore, the creases developed in the stomach wall along the band are distributed into the pockets formed between adjacent bulges which is beneficial in a physiological sense. As an alternative, such a row of bulges may also be designed on a tubing having uniform wall thickness.

Alternatively, or in combination with varying wall thickness, the same result is achieved by designing said two axially extending wall portions with different elasticity, whereby the more elastic portion is located on the inner side of the band loop.

Advantageously, one of said two opposite axially extending portions of the circumferential elastic wall, which is intended to form the inner side of the band loop, may be pretensioned.

The means for forming a loop of the band may comprise two separate locking elements stronger than the tubing secured to the tubing at opposite ends thereof. Alternatively, the locking elements may form integral parts of the tubing itself and be of the same material as the tubing. More specifically, the locking elements may be designed to be joined to each other by suturing, snap-lock connection, or the like.

The means for inflating and deflating the tubing may suitably comprise fluid distribution means for adding fluid to and withdrawing fluid from the interior of the tubing.

The invention is described in more detail in the following with reference to the accompanying drawings, in which

Figure 1 is a perspective view which schematically shows a reinforced food intake restriction device in place on the stomach and esophagus following surgical implantation,

Figure 2 presents a schematic perspective view of the device shown in Fig. 1,

Figure 3 is a view of a band of a first embodiment of the food intake restriction device according to the present invention,

Figure 4 is a cross-section along the line V-V in Fig. 3,

Figure 5 is a cross-section through a modification of the band shown in Fig. 3 and forming a loop,

Figure 6 is a cross-section through another modification of the band shown in Fig. 3 and forming a loop,

and

Figures 7 and 8 are a front view and a side view, respectively, of a band of a second embodiment of the food intake restriction device according to the present invention.

5 A reinforced food intake restriction device, which is subject of U.S. Patent Application No. 532,357 filed 1995, now U.S. Patent No. 5,771,903, will now be described with reference to Figs. 1 and 2. This device comprises a band 11, having a separate supporting elongated outer wall 13 of a
10 substantially non-expansible and flexible material. Said wall 13 is preferably made of a reinforced plastic and/or silicone material and has such a flexibility that it could be bent to form a closed loop defining a restriction opening. The band 11 has a length enabling said closed loop of the band to be
15 formed around the esophagus and/or stomach, and enabling an anterior upper part of the stomach wall to be pulled through said loop to form a small pouch 5 of the stomach. The ends 15, 17 of the outer wall 13 may be joined to each other, e.g. by suturing, by a snap-lock connection, or by any other suitable joining means.

20 The band 11 has an inner wall 19 made of an elastic, soft plastic and/or silicone material. Said inner wall 19 is glued or heat-sealed to the outer wall 13, thereby providing an expansible cavity between the walls 13, 19. The lateral
25 extension of the elongated inner wall 19 in a fully inflated state is more than 20 mm and less than 40 mm, whereas the lateral extension of the outer wall 13 is about 13 mm. Fluid supply means are provided for adding fluid to and withdrawing fluid from said cavity to expand the flexible inner wall 19
30 to decrease the size of said restriction opening and deflate the flexible inner wall 19 to increase the size of said restriction opening. The fluid supply means comprise an injection port 23 and a flexible conduit 21 connecting the injection port 23 to said cavity. The injection port 23 is
35 implanted in an easily accessible region on the patient, preferably it is placed subcutaneously against the lower part of the sternum 8, thereby providing a support for the in-

jection port 23 during fluid injection. The flexible conduit 21, which is made of a tube of silicone rubber, has a length such that when the band 11 is applied on the stomach and the injection port 23 is implanted against the sternum 8, the conduit 21 extends downwardly from both the band 11 and the sternum 8 to form an open loop there between.

The inner wall of the band 19 may be inwardly expanded from adjacent the outer wall 13 to such an extent that when a band loop has been formed, the opening of the loop will be substantially obstructed. Normally, the unexpanded loop has an inner diameter of approximately 35 mm.

The band 11 varies in width along its long axis, thereby providing a support portion 25 in the middle of the band 11 with a greater area intended to rest against the esophagus 3 (or alternatively, on the posterior part of the esophagus-cardia junction, or on the posterior surface of the cardia). In this way the surface pressure against the esophagus 3 wall (or alternatively, on the posterior part of the esophagus-cardia junction, or on the posterior surface of the cardia) will be reduced, thereby diminishing the stress per unit area placed on the esophagus 3 wall (or alternatively, on the posterior part of the esophagus-cardia junction, or on the posterior surface of the cardia) by the band 11.

The wide range of adjustment of the cavity or the inner wall 19 is a very important feature of the band 11 for accomplishing a satisfying long term result.

Fig. 3 shows a band 27 of an embodiment of the food intake restriction device of the present invention, for forming a stoma opening in the stomach or esophagus of a patient, having components similar to those of the device shown in Fig. 2, except that the band 27 is designed differently. The band 27 includes an elongated tubing 29 having a circumferential wall 31 of an elastic homogeneous material. The tubing 29 defines a closed cavity 33 with an inlet 35 for the supply of a fluid, preferably liquid. The circumferential wall 31 has a relatively thin axially extending portion 37 and a relatively thick axially extending

portion 39 situated opposite thereof. The band 27 is provided with two interconnectible locking elements 41 and 43 for forming a loop of the band 27 defining a restriction opening. The locking elements 41,43 comprise end flaps formed as integral parts of the tubing 29 itself and are of the same material as the tubing 29.

As an alternative the circumferential wall 31 of the tubing 29 may be of a pliable material and not necessarily be elastic.

Fig. 5 shows a band 45 having like components as that of the band 27 shown in Fig. 3 except that the thin portion 37 of the circumferential wall 31 is designed differently. The two locking elements 41 and 43 of the band 45 are interconnected, so that the band 45 forms a loop with the thin portion 37 of the wall 31 extending innermost along said loop and consequently, with the thick portion 39 extending outermost along said loop. The thin portion 37 is designed to form a row of bulges 47 including at least three bulges 47, here there are five bulges 47, along the band 45. The bulges 47 are completely extended and adjacent bulges 47 are spaced apart from each other when the cavity 33 of the band 45 is filled with fluid.

Fig. 6 shows a band 49 having like components as that of the band 45 except that the circumferential wall 31 is uniformly thick and designed to form a number of interconnected but spaced apart spherical portions 51, here five portions 51, along the band 49.

Fig. 7 and 8 show a band 59 of another embodiment of the food intake restriction device of the present invention having components similar to those of the device described above in connection with Figs. 3 and 4, except that said means for forming a loop of the band 59 (the locking elements 41,43 of band 27) are designed differently. Thus, two separate locking elements 61 and 63 stronger than the tubing 29 are secured, for instance by gluing, welding or the like, to the tubing 29 at opposite ends thereof, leaving a substantial longitudinal portion of the tubing 29 free between the end

flaps 61,63. Each locking element 61,63 is secured to the same longitudinal side of the tubing 29, so that the entire opposite longitudinal side of the tubing 29 has a smooth surface suited for abutment against the stomach and/or

5 esophagus. The locking element 61 is insertable into a hole 65 in the other locking element 63, so that the edge surrounding the hole 65 of the locking element 63 snaps into two lateral indentations 67 formed on the locking element 61. A sleeve 69 extends through the hole 65 and is glued on an

10 edge surrounding an opening into the tubing 29. A pipe 71 is sealingly attached to the sleeve 69 for distributing fluid to and from the interior of the tubing 29.

Claims

1. A food intake restriction device for forming a stoma opening in the stomach or esophagus of a patient, comprising
5 a band (27,59), and means (41,43;61,63) for forming a loop of the band defining a restriction opening, **characterised in** that the band (27,59) comprises a single elongated closed tubing (29) which is devoid of any longitudinally extending reinforcement means at least along a substantial longitudinal
10 portion of the tubing, and that means (35) are provided for inflating and deflating the tubing to adjust the size of said restriction opening.

2. A food intake restriction device according to claim 1,
15 wherein the tubing (29) has a pliable circumferential wall (31).

3. A food intake restriction device according to claim 2,
20 wherein the circumferential wall (31) of the tubing (29) is elastic, whereby the band (27,59) is extensible.

4. A food intake restriction device according to any of claims 1-3, wherein the tubing (29) has a homogeneous circumferential wall (31).
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5. A food intake restriction device according to any of claims 1-4, wherein the tubing has a circumferential wall (31), the thickness of which varies in the circumferential direction.
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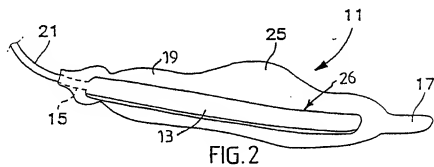
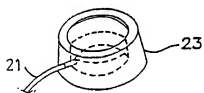
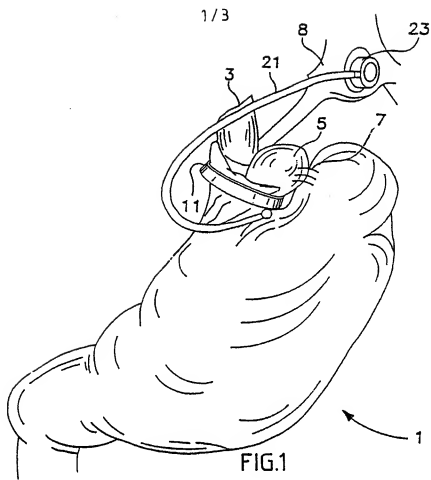
6. A food intake restriction device according to claim 5, wherein the thickness of the circumferential wall (31) of the tubing (29) varies continuously in the circumferential direction.
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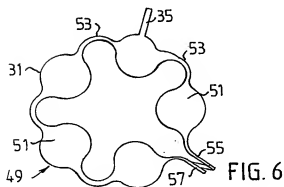
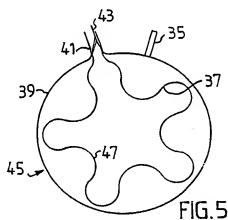
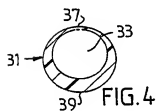
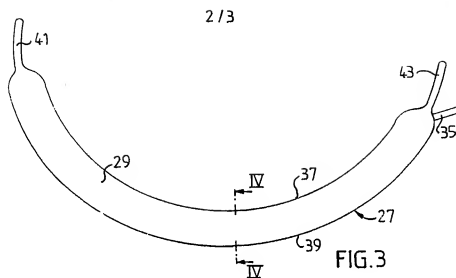
7. A food intake restriction device according to claim 5, wherein two opposite axially extending portions (37,39) of

the circumferential wall (31) differ in thickness.

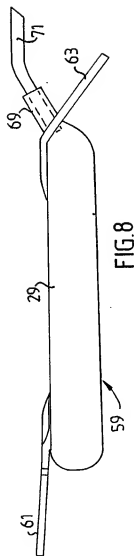
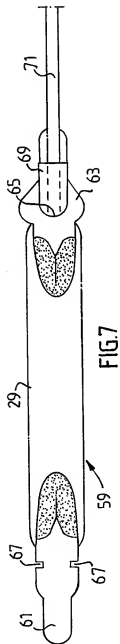
- 5 8. A food intake restriction device according to claim 7, wherein the thinner one (37) of said two opposite axially extending portions (37,39) of the circumferential wall (31) is designed to form a row of bulges (47) along the band (27,59), when said cavity (33) is at least partly filled with fluid.
- 10 9. A food intake restriction device according to claim 8, wherein the bulges (47) of the circumferential wall (31) are spaced apart from one another.
- 15 10. A food intake restriction device according to claim 3, wherein two opposite axially extending portions (37,39) of the circumferential wall (31) have different elasticity.
- 20 11. A food intake restriction device according to claim 3, wherein one of two opposite axially extending portions (37, 39) of the circumferential wall (31) is pretensioned.
- 25 12. A food intake restriction device according to claim 1, wherein the tubing (29) has a circumferential wall (31), and one of two opposite axially extending portions (37,39) of the circumferential wall is designed to form a row of bulges (47) along the band (27,59), when the tubing is at least partly filled with fluid.
- 30 13. A food intake restriction device according to any of the preceding claims, wherein the means for forming a loop of the band comprise two separate locking elements (61,63) stronger than the tubing (29) secured to the tubing at opposite ends thereof.
- 35 14. A food intake restriction device according to any of the preceding claims, wherein the means for inflating and deflating the tubing (29) comprise fluid distribution means

(35) for adding fluid to and withdrawing fluid from the interior of the tubing.





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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01134

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0769282 A1 (KIRK PROMOTIONS LIMITED), 23 April 1997 (23.04.97) --	1-14
A	US 3875928 A (J.P. ANGELCHIK), 8 April 1975 (08.04.75) -- -----	1-14

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date in another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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INTERNATIONAL SEARCH REPORT
Information on patent family members

28/09/99

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Patent document cited in search report			Publication date	Patent family member(s)	Publication date
EP	0769282	A1	23/04/97	US 5771903 A	30/06/98
US	3875928	A	08/04/75	NONE	